

REMARKS

Claims 1-29 and 34-36 are presently pending in the application.

The Office Action rejected claims 1, 2, 4, 5, 14-17, 21, 22, 34-36 and 51 under 35 U.S.C. § 102(b) as allegedly being anticipated by Arm et al. (WO 93/20859). The Office Action also rejected claims 1, 4, 7-18, 21 and 22 under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Hossainy et al. (Patent 6,451,373, published 9/17/02), rejected claims 1, 4, 7, 13-23, 25, 29 and 34-36 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lahtinen et al. (Publication 2003/0059463, published 3/27/03), rejected claims 1, 3, 4, 5, 21-28 and 51 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ledergerber (Patent 4,955,907, published 9/11/1990) in view of Schneider (Patent 3,636,956, published 1/25/1972), and further rejected claim 6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ledergerber in view of Schneider and further in view of Vijayan et al. (Patent 5,047,054, published 09/10/91). Applicants respectfully traverse these rejections, for the following reasons.

I. § 102(b) Rejection of Claim 1 Using Arm et al. Improper Since No Disclosure of “Non-Porous” Membrane

The Arm et al. reference discloses placing its alleged “PLA” membrane only into rabbits, not humans as claimed in the current application. Even for rabbits, Arm et al. recommends that such membranes NOT be used as they are not suitable for any of the Arm et al. disclosed objectives. Arm et al. clearly does not disclose the current combination of claim limitations defining a method of attenuating adhesions “in a human” including, among other things, providing a resorbable thin membrane disposed around an implant the resorbable thin membrane being non-porous and consisting essentially of a lactide polymer or a copolymer of two or more cyclic esters; applying the implant within a human; and attenuating adhesions within the human. This combination of limitations certainly is not disclosed by Arm et al. so that the Office Action’s anticipatory rejection should not stand.

Additionally, regarding the claimed “nonporous” film characteristic of claim 1, page 3 of the Office Action states that Arm et al. is “silent to this,” but Applicants disagree, and direct the Examiner’s attention to page 11 of the Arm et al. disclosure which indicates the carriers of that invention as being capable of creating pores in the film. That same page also states that the Arm et al. films are designed to promote tissue growth or infiltration, which language clearly denotes a requirement of pores. Furthermore, the Examiner’s conclusory approach of considering all lactide implants as being non-porous is clearly without merit, as can be readily ascertained by conducting a keyword search in any relevant electronic database such as the Internet or the USPTO patent database for porous lactide implants. In contrast, the current claim 1 of Applicants is directed to, among other things, membranes that are substantially non-porous. Thus, the nonporous structure of claim 1 and those dependent therefrom are not anticipated.

II. § 102(b) Rejection of Claim 1 Using Arm et al. Improper Since No Disclosure of Claimed Implant Material

This entire Section “II” is reproduced from Applicants’ prior submission. Applicants would like to direct the Examiner’s attention to various passages in Applicants’ specification which emphasize an aspect of the current invention in which the membranes comprise a layer of polymer base material selected from the group consisting essentially of a lactide polymer and a copolymer of two or more cyclic esters. Applicants’ Background of the Invention section, for example, states that “[o]ne approach to the problem of adhesion has been the use of bioresorbable barrier materials, in the form of...coatings,...films, and the like, that are placed between a healing post-surgical site and adjacent surrounding tissue.” Clearly, Applicants’ presently claimed invention is not directed to such a broad concept as any and all bioresorbable coatings on implants.

Applicants’ Background of the Invention section, furthermore, references several prior-art disclosures which are characterized as disclosing methods for coating implants to address the problem of foreign body reactions. Such prior-art devices are distinguished from the currently claimed invention, as a result of, among other things, the prior-art devices taking too long to resorb,

being insufficiently malleable, or requiring complex chemical formulations and/or reactions which may increase the cost of manufacturing.

The second paragraph in Applicants' Summary of the Invention section describes membranes according to an aspect of the current invention as scar tissue-reduction barrier membranes which are constructed entirely of resorbable polymers, and selected from the group consisting of lactide polymers (e.g., copolymers) of two or more lactides. Applicants submit that reducing tissue growth (i.e., scars or adhesions) is disclosed throughout Applicants' application as a primary objective of the invention.

Concerning the Office Action's contention that page 3, line 36 and 37, and page 4, lines 1-8, of Arm et al. teach a film of 100% polylactic acid (wherein the addition of a carrier and peptide growth factor to that film is allegedly disclosed as just a preferred embodiment, and not required), Applicants must respectfully disagree. Regarding the reasoning for Applicants' disagreement, page 3, lines 33-35 of Arm et al. initially describe "sustained release compositions for the therapeutic delivery of polypeptide growth factors," and, then, the next lines 36 and 37 follow-up by further describing "[t]he compositions" (emphasis added) as being biodegradable. That is, those lines 36 and 37 are not describing just any compositions, or compositions in general, but, rather, are specifically referring back to and further describing "the" compositions that were just discussed in the preceding lines 33-35. Now, the compositions of the Arm et al. invention are described in those lines 36 and 37 as being "for the therapeutic delivery of polypeptide growth factors." Of course, as mentioned, in order to deliver the growth factors, the films of Arm et al. would appear, in the context of that invention, to need to contain the growth factors. The following page 4, lines 1-8 of Arm et al. describes the film of that invention as containing, at least, a copolymer, one or more polypeptide growth factors, and a carrier.

Furthermore, in connection with the Office Action's statement that Arm et al. discloses 100% polylactic acid film," Applicants respond that this construction is not regarded by that disclosure as useful and, to the contrary, is characterized on more than one occasion in the in Arm et al. disclosure, that construction is discredited and dismissed as a "sham" (emphasis added, cf. page 18, line 32 and page 19, line 17).

Being limited to “compositions ... in the form of biodegradable polyester films ..., one or more peptide growth factors, and a carrier” (emphasis added), the Arm et al. reference actually teaches away from use of a 100% polylactic acid film coating on an implant, because, according to Arm et al., such structure will not work. Moreover, to the extent one of the growth-factor films of Arm et al. were to be provided on an implant (e.g., a screw), that film would actually work to encourage tissue growth, rather than to impede it. Regarding page 4 of the Office Action and the allegation that “Arm et al. do in fact...disclose...100% polylactic acid film,” Applicants request that the Examiner point out, for example, where such film is disclosed as being non-porous and disposed over more than just “only one side” of the implant. Since such identifications, among others, cannot be made, Claim 1 and those dependent therefrom thus are not anticipated.

III. Restriction Requirement Already Deemed Claims As “Patentably Distinct” Over Hossainy et al.

This entire Section “III” is reproduced from Applicants’ prior submission. Page 3 of a Restriction Requirement mailed September 6, 2006 split-up the originally-filed claims into “patentably distinct” species and required Applicants to elect “a single disclosed species...to which the claims shall be restricted” (emphasis added). In particular, the Applicants were required to elect “a single disclosed implant such as heart valves and a single disclosed surrounding tissue such as pericardium.”

In response to the Restriction Requirement’s instruction that the Applicants must elect “a single species for prosecution on the merits” (emphasis added), the Applicants elected for examination the species of artificial organs surrounded by soft tissues. Following Applicants’ election, the Office Action proceeded to search and uncover Hossainy et al., which is directed to a non-elected species, namely, “stents and grafts” surrounded by “vessel walls.” The Applicants did not elect “stents and grafts,” nor did the Applicants elect “vessel walls.” Accordingly, since the relied-upon prior art in the Office Action is directed to a non-elected species, rather than “artificial organs surrounded by soft tissues. Applicants request that all rejections based upon that prior art be withdrawn as being directed to a non-elected species.

IV. Section 2111.03[R-3] of MPEP Does Not Apply in View of Applicants' Clear Indication of
Invention Over Asserted And Synergistic Features

This entire Section "IV" is reproduced from Applicants' prior submission with the exception of language referencing exhibits. The Office Action cited to Section 2111.03[R-3] of the MPEP for a con-patent proposition, allegedly that, "absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising.'" More particularly, on page 8 of the Office Action, the Examiner in his rejection appeared to challenge the Applicants to show that the Hossainy et al. "carrier [and] compound such as actinomycin would materially affect the basic or novel characteristic of the instantly claimed invention."

A. General Considerations

Initially, with regard to general anti-scarring barrier considerations of the present invention, Applicants direct the Examiner's attention to Provisional Application 60/196,869, filed March 10, 2000. (The current application incorporates by reference Provisional Application 60/409,137, which incorporates by reference Application 09/805,411, which incorporates by reference Provisional Application 60/196,869.) That last page summarizes a number of anti-scarring tests that were performed on a number of materials and constructions, with the currently claimed one appearing to outperform the others.

In connection with this data, Applicants' Background describes how prior-art coatings and other barriers have met with limited success. For instance, as also discussed in Provisional Application 60/196,869, Applicants' Background describes how some of the prior-art barrier materials may be resorbed into the body too quickly, yielding undesirable drops in local pH levels, which may cause or exacerbate such problems as local inflammation, discomfort and/or foreign antibody responses. Other materials may take too long to resorb, may be insufficiently malleable, or may require complex chemical formulations and/or reactions which can increase the cost of manufacturing. Furthermore, the Detailed Description of the current application describes, in the text referencing Fig. 1, a method of applying a non-porous film formed of a single layer of polylactide material to maintain a smooth-faced barrier between an implant and surrounding

tissues. Such features of the present invention, including, among others, resorption time, smoothness, and non-porosity, are synergistic, and were not arbitrarily thrown together from a laundry list of attributes or features. The unique combinations include the provision of a simple-to-make (e.g., from simple compositions/reactions; cf. Pub. US07/0116739, par. 0007 and 0008) anti-adhesive membrane that offers reduction in both chemical tissue inflammation (e.g., the membrane is ultra-thin, for less inflammation during resorption; cf. Pub. US07/0116739, par. 0051) and mechanical tissue inflammation (e.g., non-leaking barrier, smooth, non-porous, cf. Pub. US07/0116739, par. 0047 and 0050; yet strong enough to have value and versatility; cf. par. 0031 and 0032, 0043). Pre-implantation stretching at glass transition temperatures (i.e., biasing) facilitates shrink-wrapping of the fragile, ultra-thin membranes (c.f. Pub. US07/0116739, par. 0035 and 0036), in an advantageous and novel fashion, around implants. For instance, when positioned around an implant and brought to its glass transition temperature, the present membrane returns, under its own memory, to its pre-biased or pre-stretched configuration, thereby contracting around and, optimally, smoothly enveloping (for less tissue turbulence), the implant.

B. Particular Considerations

Furthermore, with regard to particular anti-scarring barrier considerations raised by the Examiner, such as on page 8 of the outstanding Office Action, Applicants submit that a carrier and an actinomycin compound, such as allegedly taught by Hossainy et al., would materially affect the basic or novel characteristic of the instantly claimed invention. As exemplified on the last page of Provisional Application 60/196,869, and in various other places including, for example, the first paragraph of the Summary of the current application, a purpose of the implants of the presently claimed invention is to prevent undesired reactions between the implant and surrounding tissues. This purpose would not be met with the relatively reactionary and toxic actinomycin compound of Hossainy et al. The Examiner's attention is directed to information previously submitted by Applicants for information on the Hossainy et al. actinomycin compound. Accordingly, Applicants' "consisting essentially of" claim language should be construed true to its intended, non-skewed meaning, and the rejection based upon Hossainy et al. should be withdrawn.

V. § 103(a) Rejection of Claim 1 Using Lahtinen Improper Since No Disclosure of Non-Porous Claimed Implant Material

Claim 51 was not rejected on this ground, and Claim 1 now contains all of the limitations of Claim 51. Thus, the outstanding rejection under 35 U.S.C. § 103(a) of claim 1, and claims dependent therefrom, is improper.

VI. § 103(a) Rejection of Claim 1 Using Ledergerber/Schneider Improper Since No Teaching of Non-Porous Claimed Implant Material

The discussion of Part I, above, is incorporated herein. Neither Ledergerber nor Schneider, taken separately or together, disclose or suggest the current combination of claim limitations particularly delineating a method for attenuating adhesions in a human including, among other things, providing a resorbable thin membrane around an implant the resorbable thin membrane being non-porous and consisting essentially of a lactide polymer or a copolymer of two or more cyclic esters, applying the implant within a human, and attenuating adhesions within the human. This combination of limitations certainly is not disclosed or suggested by the prior art of record. Accordingly, the Office Action's obviousness rejection should be reevaluated and retracted.

In this rejection, the Office Action characterizes the claimed invention as being directed to, among other things, "a method for attenuating adhesion between an implant (i.e. organ) and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding an implant" and then cites column 6, lines 57-62 of Ledergerber for disclosing "any material which promotes limited tissue ingrowth" (emphasis added; cf. page 14 of Office Action). That same paragraph of Ledergerber defines promoting limited tissue ingrowth as embodying "a high degree of ultramicroporosity which invites tissue ingrowth" and comprising "approximately 50% air by volume." The next paragraph of that reference describes the implant as comprising a "stretch weave in the form of a blind sock to permit complete envelopment of the implant" to be "held around the implant 10 by means of a drawstring," such structure hardly equating to the currently claimed "non-porous" structure.

As for Schneider, it discloses a polylactide polymer filament, but that is all. As for the quotation on page 14 of the Office Action that the Schneider polymers can be “cast into films,” those three words are taken out of context. The actual language containing the three words says that “it is possible to...cast it into films, which are then...cut into narrow strips for use as sutures.”

Accordingly, the Schneider’s filaments appear to be cumulative of the prior art already discussed in Applicants’ Background section of the current application, such as in connection with Tang et al. Moreover, there does not appear to be any motivation to combine the Ledergerber tissue-ingrowth socks with the Schneider suture filaments, and, even if there were, any conceivable combination would be nonsensical and certainly would not yield Applicants’ combinations of claimed elements.

The Office Action’s statement that “one would have been motivated to do so because Ledergerber teaches that any material that impedes tissue in-growth...can be used as a covering” is clearly misleading since, as established above, Ledergerber teaches using “material[s] which promote...tissue ingrowth” (emphasis added), rather than impede it.

The Office Action gives, as another motivation-to-combine, the isolated, conclusive statement that “[o]ne would further be motivated to use the film sheet of Schneider [with Ledergerber’s tissue ingrowth implant] because the film taught by Schneider is bioabsorbable.” First, in the context of this rejection, what does “bioabsorbable” have to do with anything, as the Office Action appears to give no relevance or nexus between this feature and Ledergerber’s implants. Does Ledergerber mention somewhere a need or desire for bioabsorbable implants? Secondly, it was already established above that Schneider does not even disclose “films” but rather films cut-up into strips to form sutures. Indeed, it seems that the implants allegedly taught by Schneider do not appear to be directed to promoting tissue ingrowth (which, for compatibility, is the focus of Ledergerber), do not appear to be directed to covering implants (which may be a focus of Ledergerber), and furthermore, to the extent biosorbable, do not appear to bear any nexus to the Ledergerber implants by operation of that (bioabsorbable) feature, so that, in summary, the only common thread connecting these two references would appear to be the Office Action’s hindsight. Thus, the outstanding rejection under 35 U.S.C. § 103(a) is improper.

VII. § 103(a) Rejection of Claim 6 Using Ledergerber/Schneider/Vijayan et al. Improper Since No Teaching of Claimed Heat Shrinking of Non-Porous Claimed Implant Material

This entire Section “VII” is reproduced from Applicants’ prior submission, and as with the prior submission the discussion of Part VI above is incorporated herein. In particular, since Ledergerber and Schneider are not combinable absent “hindsight” gleaned from the present application, the rejection of claim 6 based upon yet another reference, would appear to be even more nonsensical. Furthermore, as discussed in Part VI, even if, hypothetically, combinable, Ledergerber and Schneider would not come close to yielding, or suggesting, any of the currently claimed combinations.

It is well established that a claim can be rejected on obviousness grounds only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference or combination of prior-art references. Thus, for a rejection under 35 U.S.C. § 103(a) to be proper, every limitation recited in a claim, which is rejected as being obvious in view of a combination of prior-art references, must be disclosed or taught in that collection of prior-art references. In the instant case, Applicants respectfully submit that the collection of all three of the cited references neither disclose nor suggest each and every element that is recited in the rejected claims. For example, not a single one of the references discloses the claim limitation of, for example, a “method...attenuating adhesions between [a] implant and the surrounding tissues” (emphasis added), of claim 6 and its base claim 1. That is, Ledergerber is an adhesion promoting implant, Schneider is a fiber (having a shape hardly capable of the claimed attenuating of adhesions), and Vijayan is an adhesion promoting implant (see Vijayan: col. 3, lines 56, 4/55, 56; col. 5, lines 21-26; col. 6, lines 12, 13, 40-48, 54-58; col. 7, lines 37-43).

Furthermore, not a single one of the references discloses the same claim limitation of a “method...attenuating adhesions” that is further characterized by “essentially...a lactide polymer; or a copolymer of two or more cyclic esters” (emphasis added), of claim 6 and its base claim. This combination of limitations clearly is neither taught nor suggested by Ledergerber and Schneider, taken separately or together, in any combination, and, furthermore, is most certainly neither taught nor suggested by Vijayan, taken alone or in combination with any one or more of Ledergerber and Schneider. The adhesion promoting implants of Vijayan are limited to compositions consisting of

resins, along with various combinations of plasticizers and other non-claimed agents (see Vijayan: col. 3, lines 15, 16, 19, 20, 39; col. 5, lines 21-26, 46-52, 61, 62; col. 6, lines 12, 13, 40-48, 54-58; col. 7, lines 37-43), none of which in any way disclose or suggest the combinations of limitations such as recited in claim 6. Accordingly, since several of the individual limitations are nowhere present in single one or more of any of the relied-upon references, no matter how those references are combined, the missing limitations still will not be, and are not, present in any hypothetical combination of the relied-upon references.

Moreover, in addition to there being no motivation to combine the Ledergerber tissue-ingrowth implants with the Schneider suture filaments, there certainly would have been no motivation to add-in Vijayan's resin-based chemicals and agents into the Office Action's creative, hindsight-based creation. On the motivation-to-combine issue, the Office Action seemingly was a conservationist on logic. The "motivation to combine" was asserted in the current § 103(a) rejection as being, simply, "because heating the coating...would provide for a tightly adherent coating." Heating which coating? Where is there any evidence or suggestion stating that the porous, non-resin "sock" of Ledergerber or the "thread" of Schneider would benefit from "a tightly adherent coating"?

Clearly, the Office Action has not provided an adequate articulation to how the three relied-upon, quite divergent references could have been viewed as combinable by one skilled in the art. While the Office Action states that one would have been motivated to combine the references "because heating the coating...would provide for a tightly adherent coating," this makes no sense since, for instance, Vijayan uses heat to cure a resin, but Ledergerber and Schneider do not appear to seek heating as they do not even appear to use resins.

In more detail, it should be contextualized that the allegedly "heat-benefiting" implant of Ledergerber is a weaved sock with a drawstring closure, and the proffered "heat-benefiting" implant of Schneider is nothing more than a filament. Since neither of the Ledergerber and Schneider implants are resin-based in need of heat curing, no motivation, whatsoever, has been provided for combining the porous, resin-based implant teachings of Vijayan with the porous, non-resin "socks" and "threads" of Ledergerber and Schneider. Applicants request that the Examiner kindly answer, without referencing or "borrowing from" Applicants' disclosed pre-loading membrane forming techniques (cf. twelfth paragraph of Detailed Description), how

one skilled in the art would have derived any motivation to “heat” his or her membrane, and, furthermore, how a person skilled in the art would be led or, perhaps more precisely, misled, into believing that “heating” the porous, non-resin “sock” or “thread” of Ledergerber or Schneider would cause either to shrink. Also, why would either reference seek shrinkage? It is submitted that a skilled artisan would not expect heating of the Ledergerber sock or the Schneider thread to cause shrinkage, and/or advantageous shrinkage, and would be correct.

Even still, to the extent hypothetically performed, such heating of such implants, as discussed above, would not serve to “tighten” them, as asserted by the Office Action. The evidence appears to indicate that, on the motivation-to-combine issue, any combination of the Ledergerber tissue-ingrowth socks, the Schneider filaments, and the Vijayan resins, would not have been indicated, or sensible, and, to the extent hypothetically integratable, any conceivable such combination would be nonsensical or at best impracticable, and certainly would not have yielded Applicants’ combinations of elements such as recited, for example, in claim 6. Accordingly, the outstanding rejection under 35 U.S.C. § 103(a) of claim 6 is improper and should be withdrawn.

With respect to the claims not specifically mentioned above, it is submitted that each of these claims is likewise free and clear of the scope of the cited references to similar and even greater degrees, not only by virtue of its dependency upon the respective base claim but also for the totality of features recited therein.

In view of these and potentially other reasons, Applicants disagree with the Examiner’s position that the instantly claimed method of attenuating adhesions between an implant and surrounding tissues is anticipated or would have been obvious.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 and § 103. Applicants submit that the application is now in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions.

The Commissioner is hereby authorized to charge any needed fees to Deposit Account 50-1600.

Respectfully submitted,



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